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SCOPE:

- The scope of medical equipment management plan defines the processes which the University of Texas M D Anderson Cancer Center (UTMDACC includes a 512-bed main complex at the 1515 Holcombe address, it also covers offsite areas including Ambulatory Clinic Building, Cancer Prevention Clinic, Radiation Outpatient Clinic, Bellaire Treatment Center, and Radiation Treatment Center at Fort Bend, Woodlands Treatment Center, Gynecology Oncology Associates, Gynecology Oncology Outreach and Proton Treatment Center) provides for the safe and proper use of medical equipment used in the patient care setting.
- The Clinical Engineering Department provides services from 6:00 AM – 6:00 PM Monday through Friday, and emergency coverage is provided on a 24 hour, seven-day-a-week basis through use of on-call system.

OBJECTIVE:

The objective of UTMDACC's medical equipment management plan is designed to assess and control the physical and clinical risks of all equipment used in the diagnosis, treatment, monitoring and care of our patients.

GOALS:

- The goals of UTMDACC's medical equipment management plan includes the following:
    - To minimize the clinical and physical risks of equipment through inspection, testing and regular maintenance
    - To establish criteria for identifying, evaluating and inventorying equipment which is included in the program
    - To provide education to personnel on the capabilities, limitations and special applications of equipment; operating, safety and emergency procedures of equipment; the procedures to follow when reporting equipment management problems, failures and user errors; and the skills and/or information to perform maintenance activities

RESPONSIBILITY:

- The Clinical Engineering Department Director and the Clinical Engineering Managers are responsible for maintaining the Medical Equipment Management Program. Each UTMDACC department manager is responsible for orienting new staff members to the capabilities, limitations, special applications of equipment, basic operating and safety procedures, emergency procedures if failure occurs, maintenance responsibilities, if applicable, and the reporting procedures for equipment problems, failures and user errors.
- All information and data collected is aggregated by the Clinical Engineering Director. Conclusions, recommendations, actions and evaluations will be reported along with the aggregated data to the Institution Safety Committee (ISC) and other appropriate committees according to meeting schedule.

ELEMENTS OF PERFORMANCE:

THE SELECTION AND ACQUISITION OF MEDICAL EQUIPMENT:

- A needs assessment will be completed by each department for replacement or new equipment. The needs assessment will be reviewed by the Capital Equipment Committee and the Clinical Engineering Director. The Clinical Engineering Director will determine if the equipment meets appropriate space requirements, load and phase requirements, Underwriters Laboratory requirements, minimum safety standards of three (3) wire AC line cord with hospital grade plug, appropriate warranties and manufacturer's reliability prior to purchase. If the equipment does not meet the above specifications, it may not be ordered and an alternate choice may be submitted for approval.

- See Policy on Selection and Acquisition of Equipment, Incoming Equipment Checklist Form, Application for Equipment Acceptance Form, New Equipment Testing Log, Medical Equipment User/Maintainer Training Program, Medical Equipment Management Orientation/Education Policy, Medical Equipment User/Maintainer Training Log, Employee Medical Equipment Training and Competency Form.

ESTABLISHING RISK CRITERIA FOR IDENTIFYING, EVALUATING AND TAKING INVENTORY OF MEDICAL EQUIPMENT TO BE INCLUDED IN THE MEDICAL EQUIPMENT MANAGEMENT PROGRAM:

- All mechanical and electrical patient care equipment will be evaluated prior to use, based on function including diagnosis, care, treatment and monitoring; physical risks associated with use to patients and operators, maintenance requirements and history of equipment incidents. All incoming and existing equipment meeting the evaluation criteria are included in the Medical Equipment Management Program.

- All new equipment shall be inventoried and inspected prior to use for patient care or any other use. Equipment that fails electrical safety tests shall not be approved for use until the deficiencies have been corrected. There is a current inventory of all equipment included in the Medical Equipment Management Program.

- See Medical Equipment Management Policy, Equipment Management Code System, Medical Equipment Management Inventory, Inventory and Inspection of New Equipment Policy, Application for Equipment Acceptance Form, Medical Equipment Management Inventory Form, Additions to Medical Equipment Management Inventory Form and Deletions from Medical Equipment Management Inventory Form.

EQUIPMENT MAINTENANCE STRATEGIES:

- Maintenance strategies will be identified for all equipment in the inventory. Different strategies may be utilized as appropriate including predictive maintenance, interval-based inspections, corrective maintenance, metered maintenance, etc.
- Clinical Engineering uses predictive maintenance for repairs such as battery replacement. Clinical Engineering uses interval-based inspections (scheduled preventive maintenance) for those items that are identified to be Priority Levels 1,2, or 3 as defined by Equipment

Management Code System. Clinical Engineering uses metered maintenance, based on hours of use, for items such as ventilators or dialysis machines

- See Definitions of Medical Equipment Maintenance Strategies

EQUIPMENT TESTING, INSPECTING AND MAINTAINING INTERVALS:

- The equipment that is included in the inventory that would benefit from scheduled maintenance activities to minimize clinical and physical risk are based on the following criteria:
    - Manufacturer's recommendations
    - Risk levels
    - Current hospital experience
- Incident history is documented and maintained in the Engineering Department Director's office. Equipment displaying unusual repair history or unusual incidence of injury to patients or staff will be evaluated for necessary changes/replacement.
- A maintenance strategy will be developed for all medical devices in the hospital. Maintenance procedures will be developed and maintained by the Clinical Engineering Director, using the manufacturer's maintenance recommendations, NFPA and ANSI standards.

INVESTIGATION AND REPORTING OF EQUIPMENT MANAGEMENT PROBLEMS, FAILURES AND USER ERRORS:

- All equipment failures and user errors will be investigated and reported to the ISC. Included in the report will be the error/failure date, location of the equipment, cause or affected area, resolution and follow-up. In the event the equipment problem was caused by user error, the user(s) will be in-serviced on the operation and use of the equipment.
- See Equipment Safety - Reporting Malfunction Policy, Medical Equipment User/Error or Failures Log and Medical Equipment Failure/User Error Follow-up Report Form.

HAZARD NOTICES AND RECALLS:

- All product safety alerts, hazard notices and recalls will be directed to the Clinical Engineers. In the event the notices are not directed to the Clinical Engineers, the notices will be immediately rerouted to the Clinical Engineers. The Clinical Engineer will check the clinical equipment inventory to screen for equipment matches and will evaluate the severity of the risk. In most cases, the notices may be addressed without removing equipment from service. In the event equipment must be removed from service, the equipment is replaced with a safe effective substitute. The Clinical Engineering Department will impound equipment removed from use due to recall notices until it can be rendered safe.
- The Risk Manager will report quarterly to the ISC Committee on any hazard notices and recalls affecting the hospital and all follow up activities undertaken.

- See Medical Device Recall Policy and Safety Management Manual.

MONITORING AND REPORTING OF MEDICAL DEVICE INCIDENTS RESULTING IN DEATH, SERIOUS INJURY OR SERIOUS ILLNESS OF ANY INDIVIDUAL AS PER SAFE MEDICAL DEVICE ACT OF 1990:

- The Safe Medical Device Act of 1990 requires that device user facilities (including hospitals, outpatient diagnostic and treatment facilities, nursing homes, ambulatory surgical facilities) report incidents to the device manufacturer when the facility determines a device has or may have caused or contributed to the death or serious injury of an individual. The facility must also send a copy of the report to the FDA in the case of a death.

- UTMDACC has established methods for reporting these events:
    - The appropriate personnel will be notified immediately.
    - All packaging and disposable materials will be returned.
    - The device will be inspected and control settings and any damage will be recorded. The equipment will be bagged, tagged and sequestered by Security.
    - An investigation shall be conducted.
    - The Risk Manager is responsible for managing the Safe Medical Device Act reporting process.

- See Safe Medical Devices Policy.

EMERGENCY PROCEDURES:

- Equipment, which meets UTMDACC's criteria for critical to patient safety, shall have emergency procedures in the event a malfunction or failure occurs. Equipment considered critical to patient safety includes life support, life sustaining or other critical equipment whose malfunction or failure may result in an adverse patient outcome.

- Each department will develop and follow specific clinical response procedures in the event of an equipment failure:
    - Equipment will be removed from service and tagged immediately.
    - Institute clinical emergency procedures required ensuring patient care is not compromised (i.e., ventilator failure ensure an ambu bag is available until replacement equipment is brought to the patient care unit).
    - If replacement equipment is necessary, _____ (depending on the kind of equipment) will be notified to obtain a replacement.
    - The EH & S Department, Clinical Engineering Department, and Risk Manager will be notified of the failure.

- An incident report will be completed describing the failure.

- See Equipment Safety - Reporting Malfunction Policy, Emergency Procedures for Medical Equipment Failure/Disruption.

THE MEDICAL EQUIPMENT MANAGEMENT PROGRAM INCLUDES AN ORIENTATION AND EDUCATION PROGRAM FOR EQUIPMENT MAINTAINERS:

- Thorough training will be provided to equipment maintainers upon hire and as needed thereafter regarding the maintenance and care of medical equipment.

- All equipment maintainers will be tested for their knowledge and skills necessary to perform equipment repair and maintenance according to their job specifications.

- Staff will be oriented and educated on the reporting process for equipment management problems, failures and user errors.

THE MEDICAL EQUIPMENT MANAGEMENT PLAN INCLUDES A MEDICAL EQUIPMENT ORIENTATION AND EDUCATION PROGRAM FOR MEDICAL EQUIPMENT USERS:

- Thorough training will be provided regarding the capabilities, limitations, special applications of equipment, basic operating and safety procedures, emergency procedures if failure occurs, maintenance responsibilities, if applicable, and the reporting procedures for equipment problems, failures and user errors included in the program by department managers or designees in involved departments. All users of equipment shall be tested for competency according to the components of their job specifications.

- See Equipment Safety - Reporting Malfunction Policy, Competency Forms, Medical Equipment Management Orientation/Education Policy and Medical Equipment User/Maintainer Training Log.

PERFORMANCE STANDARDS:

- Performance measures with related outcomes will be established as a means to systematically monitor the identified focus areas in an ongoing manner, and to provide operational linkages between the risk management functions related to patient and staff safety and the performance improvement functions. Performance expectations will be established for any new or revised processes undertaken by the Clinicalcal Engineering Department staff. Performance measures will be specific and measurable. Performance measures will be structured to relate to both the processes and outcomes of patient and staff safety. Performance measures will pertain directly to safety practices and will use objective criteria that reflects current knowledge and expertise.

    - The following criteria will be utilized to assure that the performance measure chosen for data collection is the most appropriate for monitoring the performance of patient and staff service processes, systems or functions:

        - The measure can identify the events it was intended to identify.

- The measure has a documented numerator and a denominator statement or description of the population to which the measure is applicable.
- The measure has defined data elements and allowable values.
- The measure can detect changes in performance over time.
- The measure allows for comparison over time within the organization or between the organization and other entities.
- The data intended for collection are available.
- Results can be reported in a way that is useful to the organization and other interested stakeholders.

- The ISC Committee on an ongoing basis monitors performance regarding actual or potential risk related to one or more of the following:
  - Staff knowledge and skills
  - Level of staff participation
  - Monitoring and inspection activities
  - Emergency and incident reporting
  - Inspection, preventive maintenance and testing of safety equipment

- Other performance measures and outcomes will be established by the ISC, based on the criterion listed above. Data sources, frequency of data collection, individual(s) responsible for data collection, aggregation and reporting will be determined by the ISC.

- To identify opportunities for improvement, the ISC will follow the organization's improvement methodology, the PDCA model. The basic steps to this model will consistently be followed and include planning, designing, measuring, analyzing/assessing, improving and evaluating effectiveness.

- Should the ISC feel a team approach (other than the ISC) is necessary for performance and process improvement to occur, the ISC will follow the organization's performance improvement guidelines for improvement team member selection. Determination of team necessity will be based on those priority issues listed (high-risk, volume and problem prone situations and sentinel event occurrence). The ISC will review the necessity of team development, requesting team participation only in those instances where it is felt the ISC's contributions toward improvement would be limited (due to specialty, limited scope and/or knowledge of the subject matter). Should team development be deemed necessary, primarily, team members will be selected on the basis of their knowledge of the subject identified for improvement, and those individuals who are "closest" to the subject identified. The team will be interdisciplinary, as appropriate to the subject to be improved.

- Performance improvement monitoring and outcome activities will be presented to the ISC by the Clinical Engineering Department Director at least on a quarterly basis, with a report

of performance outcome forwarded to the Organizational Performance Improvement Committee, Medical Executive Committee and Governing Body quarterly.

- The following performance measures are recommended:
    - Percent of staff able to demonstrate their knowledge and skill of their role and expected participation in the medical equipment management plan
    - Percent of performance assessments/evaluations reflecting competence to provide service
    - Number of equipment incidents reported
    - Percent of PM's completed on time
    - Number of user error and follow-up training with improved outcome.
    - Percent of employee training in equipment operation and competency verification at the department level.
- See Clinical Engineering Department Performance Improvement Plan and Clinical Engineering Department Performance Measures.

ANNUAL EVALUATION OF THE MEDICAL EQUIPMENT MANAGEMENT PLAN/PROGRAM:

- The annual evaluation of the medical equipment management plan/program will include a review of the scope according to the current TJC standards to evaluate the degree in which the program meets accreditation standards and the current risk assessment of the hospital. A comparison of the expectations and actual results of the program will be evaluated to determine if the goals and objectives of the program were met. The overall performance of the program will be reviewed by evaluating the results of performance improvement outcomes. The overall effectiveness of the program will be evaluated by determining the degree that expectations where met.
- The performance and effectiveness of the medical equipment management plan/program shall be reviewed by the ISC Committee.
- See Annual Evaluation of the Effectiveness of the Medical Equipment Management Plan/ Program.

02 Biomedical Equipment Management (Medical Equipment Management Code Number)

POLICY:

All electromechanical patient care equipment will be evaluated prior to use based on function, physical risks associated with clinical use, maintenance requirements and equipment incidents. All incoming and existing equipment meeting the evaluation criteria are included in the medical equipment management program. An inventory of equipment included in the program and equipment maintenance records documenting all maintenance on equipment is kept in the TMS Enterprise site in Server: UTMBIOMED2NT; Data Base: TMSMDABIO.

PROCEDURE:

- All biomedical equipment is evaluated on function, risk, maintenance requirements and equipment history. Each piece of equipment is assigned an equipment management number.
  - Equipment Function shall be divided into four (4) groups:
    - Therapeutic
    - Diagnostic
    - Analytical
    - Miscellaneous
  - Physical Risk associated with application is evaluated on the following criteria:
    - Patient death
    - Patient or operator injury
    - Inappropriate therapy or misdiagnosis
    - No significant risks
  - Maintenance Requirements are evaluated on the following criteria:
    - Extensive:
      - Includes equipment that requires routine alignment, calibration or extensive parts replacement.
    - Above Average:
      - Includes equipment requiring preventive maintenance a minimum of every six (6) months.

- Average:
  - Includes equipment that needs only performance verification and Electrical Safety Inspection (ESI).
- Below Average:
  - Includes equipment that receives only a visual inspection, basic performance test and safety testing is minimal.
- Minimal:
    - Includes equipment that does not require preventive maintenance.

- Equipment history and incidents involving injuries or deaths will be used to assist in evaluating equipment.
- All equipment not included in the inventory will be inspected every time it requires corrective maintenance.
- The Clinical Engineering Department will maintain an inventory of all equipment included in the medical equipment management program. The inventory will include function value, risk value, maintenance value, equipment management number and preventive maintenance interval.
- All incoming equipment will be compared to an included device list.
- Summary Reports are available upon request to all department managers/directors in which equipment is used.
- Equipment evaluation results shall be reported for review by the Institutional Safety Committee (ISC). Any changes to the medical equipment management program must be approved by the ISC.

03 SELECTION AND ACQUISITION OF EQUIPMENT

PURPOSE:

Ensure that medical equipment under consideration for use in the Institution is evaluated prior to purchase, lease or rental.

POLICY:

All medical devices, including replacement and new equipment, will be based on a needs assessment completed by the individual department requesting the equipment. The Clinical Engineering Department, in conjunction with nursing, medical staff and other relevant departments, will evaluate equipment before acquisition.

PROCEDURE:

- The requesting department will complete a needs assessment for the selected equipment and submit the request to the Capital Equipment Committee for review.
- The Capital Equipment Committee will review the needs assessment to determine if the purchase is justified.
- The equipment will be evaluated for:
    - Safety
    - Infection control
    - Clinical effectiveness
    - Compliance with manufacturer's specification and codes and standards
    - Compatibility with existing equipment/systems
    - Ergonomic and operational factors
    - Maintenance and operating costs throughout equipment's life
- The Clinical Engineering Department Director will review the equipment prior to purchase to ensure it meets a minimum of the following requirements:
    - Appropriate space requirements
    - Load and phase requirements
    - Underwriters Laboratory requirements
    - Minimum safety standards of three (3) wire AC line cord with hospital grade plug

- Appropriate warranties and manufacturer's reliability

- If the equipment does not meet the above listed specifications, it may not be ordered. An alternate choice will be submitted to the committee and the Engineering Department Director for approval.

- The equipment will be evaluated prior to use according to the established criteria by the Clinical Engineering Department.

- The clinical staff will receive device-specific orientation and training prior to the equipment being released for patient care use. All training is documented and kept on file in the employee's personnel file.

- A copy of the manufacturer's operator manuals and instructions are accessible to personnel to review at the location of the equipment and in the Clinical Engineering Department.

04 EQUIPMENT MANAGEMENT CODE SYSTEM

The following is a sample formula to meet requirements of evaluating equipment to include in the preventive maintenance program.

EQUIPMENT FUNCTION:

Life Support 10
Surgical and Special Care Units 9
Physical Therapy and Treatment 8
Surgical and Special Care Monitoring 7
Physiological Monitoring and Diagnostic 6
Analytical Lab 5
Laboratory Accessories 4
Computer and Related.....3
Patient Related and Other 2
Non-Patient Related 1

PHYSICAL RISK:

Patient Death 5
Patient or Operator Injury.....4
Inappropriate Therapy or Misdiagnosis.....3
.....2
No Significant Risk.....1

MAINTENANCE REQUIREMENT (EQUIPMENT HISTORY):

Extensive 5
Above Average 4
Average 3
Below Average.....2
Minimal 1

A Clinical Engineer will evaluate equipment to come up with the Equipment Management Code (EMC). The formula below can be used for equipment evaluation.

Equipment Management Code (EMC) is assigned according to the following formula:

EMC = Function + Risk + Maintenance Requirement

EMC	Priority	Preventive Maintenance Interval
Greater than or equal to 16	1. Life Support	Minimum of 2 pms per year
12 to 15	2. Non-LS, Direct Patient Care.	Minimum of 1 pm per year
11 or less	3. Non-LS, Indirect Patient Care	Removed from Inclusion Program Minimum of 1 pm per year
	4. Laboratory Equipment (CAP)	

05 DEFINITIONS OF MEDICAL EQUIPMENT MAINTENANCE STRATEGIES:

- Preventive Maintenance:

  Maintenance strategy based on a schedule or timetable. Utilizing the equipment management code, equipment is evaluated for function, physical risk and maintenance requirement. The code assigned the piece of equipment determines the frequency of preventive maintenance checks, i.e., visual inspection, bearings are lubricated, cords are checked.

- Predictive Maintenance:

  Maintenance strategy that provides the means to achieve reliability levels that exceed the performance of a piece of equipment or system. Predictive analysis programs are based on metrics, which is measuring and tracking of data significant to the piece of equipment or system. It confirms possible faults with the equipment and specific repairs are completed before the equipment fails. Predictive analysis can be performed by advanced monitoring instruments and predictive software that collects data and performs an analysis. A predictive maintenance program targets equipment maintenance that could compromise performance or safety. The data collected is analyzed and corrective maintenance is performed when the equipment is performing outside of the desired operating parameters.

- Metered Maintenance:

  Maintenance strategy based on the hours of run time or the number of times the equipment is used, i.e., number of images processed.

- Corrective Maintenance:

  Maintenance strategy that restores a piece of equipment to operational status after equipment failure.

- Interval-based Inspections:

  Maintenance done according to specific intervals, i.e., calendar time, running hours. A number of periodic inspections or restoration tasks based on information/data obtained from the last equipment check.

Note: Any maintenance strategy utilized should be based on manufacturers' recommendations, risk levels and current organizational experience.

06 PREVENTIVE MAINTENANCE

POLICY:

- To maintain a comprehensive preventive maintenance program, which includes written testing and maintenance for all equipment included in the program at established intervals. It is the responsibility of the Clinical Engineering Director to keep the preventive maintenance program accurate and ongoing.

- Documentation of the preventive maintenance program is located in the following UTMDACC Server: UTMBIOMED2NT; Data Base: TMSMDABIO.

- Equipment included in the program shall meet one (1) or more of the following criteria:

    - The equipment is essential for life support or is used in diagnosing or monitoring any physiologic condition of the patient.

    - The equipment has a higher than normal incident risk during routine operation due to clinical application.

    - The equipment requires a more intensive maintenance schedule, by reason of its complexity or use factor.

    - Equipment incident history requires intensified monitoring.

    - The equipment is supplied or maintained by outside vendor.

PROCEDURES:

- The Clinical Engineer will develop preventive maintenance procedures for all medical devices that are serviced by the Clinical Engineering Department. The preventive maintenance procedures are developed using the specific device's manufacturer's preventive maintenance recommendations, NFPA standards and AHA standards.

- At the beginning of each month, the TMS program issues the scheduled maintenance work orders to the Biomedical Equipment Technicians (BMET).

- Maintenance is performed in accordance with the instructions included in the work order. The assigned BMET shall document the maintenance, including any pertinent observations, on the work order. When

maintenance and documentation are completed the BMET will mark complete in the TMS work order module.

- If scheduled maintenance cannot be performed (i.e., part not available), the reason is documented on the work order with the appropriate code. The work order is placed under "outstanding jobs", which will later be compiled as part of the Back Log report.

- If equipment must be removed from the user area for more than one (1) day, the BMET shall prepare a corrective maintenance order. And advice the person in charge of the department from which the equipment was removed.

- If scheduled maintenance is to be performed by an external vendor, the BMET contacts the vendor and instructs the vendor to perform the maintenance as detailed in the work order, document the maintenance and any associated work done on the work order and return the equipment to use.

09 MEDICAL DEVICE RECALL

POLICY:

The following mechanism shall be utilized by UTMDACC to notify departments of any product safety alerts, hazard notices and/or device recalls from governmental agencies and manufacturers.

PROCEDURE:

- All notifications received are to be forwarded immediately to the Core Management Group of the Clinical Engineering Department.

- Any notice received by another department will be immediately forwarded to the Clinical Engineering Department.

- The Clinical Engineer (CE) will check the clinical equipment inventory to screen for equipment matches and will evaluate the severity of the risk.

    - The CE will dispense the notice to any/all appropriate departments involved by nature of using the material/device/medication.

- The department(s) receiving the Recall Notices will:

    - Implement the information provided in the Recall Notice.

    - Place each in their department's under the Recall Notices section.

- In the event equipment must be removed from service, the equipment is replaced with a safe effective substitute. The Clinical Engineering Department will impound equipment removed from use until it can be rendered safe for use.

- The EH & S Department is responsible for contacting any/all departments utilizing the material(s)/device(s)/medication(s) to confirm their compliance with the Recall Notice.

- Clinical Engineering reports the following in the monthly ISC report:

    - Recall Notices received

    - Action taken by the departments utilizing the material(s)/device(s)/medication(s)

11 EQUIPMENT SAFETY REPORTING MALFUNCTION

POLICY:

When equipment malfunctions, the following reporting procedure will be followed.

PROCEDURE:

- The Department requesting service will call **3-5000**.
- Equipment Malfunctions - Patient Care Equipment
  - When a malfunction is evident, the following steps shall be taken:
    - Double check procedure techniques to ascertain whether there is a true malfunction or a procedural error.
    - If the malfunction continues to occur, remove equipment from service and tag it immediately, call 3-5000.
    - If this is an emergency:
      - Institute clinical emergency procedures required to ensure patient care is not compromised. Notify 3-5000. Let them know equipment is malfunctioning.

13 INVENTORY AND INSPECTION OF NEW EQUIPMENT

POLICY:

It is the policy of UTMDACC to take all necessary safety precautions when new equipment is purchased for installation in the hospital. All new equipment shall be inventoried and inspected prior to use for patient care or any other use, including radiology, ultrasound and nuclear imaging equipment and clinical laboratory equipment. New equipment that fails electrical safety tests shall not be approved for use until the deficiencies have been corrected.

PROCEDURE:

- All requests for new equipment shall be reviewed and approved for proper safety features, including electrical needs, space consideration, OSHA requirements, etc., by the Clinical Engineering Department.

- After receipt of any new equipment, but prior to its installation, equipment must be inspected. Electrical and mechanical tests shall be performed and the Clinical Engineering Department shall determine that it meets all appropriate safety standards. After passing inspection, the new equipment is assigned an identification number and is placed on a maintenance schedule.

- When equipment is assigned an identification number, the BMET performing the inspection will document the inspection and the date the inspection was performed in the comment section of the equipment form.

- If the equipment fails to pass the required tests and inspection, the BMET will return the equipment to the vendor until the deficiency is corrected. The equipment is not assigned an identification number until the equipment has passed all the requirements.

- In the event that items of equipment not belonging to the hospital are brought into the hospital for use, they must be inspected and determined to be safe by the Clinical Engineering Department. This would apply to items brought by patients, visitors or employees (radios, televisions, coffee makers, etc.). The Clinical Engineering Department Director is authorized to remove any item which is found to be unsafe for use in the hospital. This will include any and all demonstration equipment brought in by any vendor.

- It shall be the responsibility of the Clinical Engineering Department to routinely inspect all pertinent hospital equipment to determine it's safe

operation. If deficiencies are found, the Engineering Department shall notify the affected department manager and implement corrective measures.

15 MEDICAL EQUIPMENT MANAGEMENT INVENTORY SAMPLE

Asset #	Manufacturer	Description	Model #	Serial #	Account Code	Department	Location	Original Cost	Date Purchased
504477	ACUSON CORP A SIEMENS CO	SCANNING SYSTEMS, ULTRASONIC, GENERAL PURPOSE	08267697	64917	18023920-CARDI	CARDIOLOGY	R8.2198B	$112,000.00	02/02/05
504576	PHILIPS MED SYS CARDI & MON SYS	SCANNING SYSTEMS, ULTRASONIC	M2424A	US90312968	18023920-CARDI	CARDIOLOGY	R8.2190	$191,837.00	09/26/03
504577	PHILIPS MED SYS CARDI & MON SYS	ELECTROCARDIOGRAPHS, MULTICHANNEL	860284	US60401754	18023920-CARDI	CARDIOLOGY	G3.3453	$13,900.00	12/07/04
510514	SIEMENS MED SYS INC ULTRASOUND	SCANNING SYSTEMS, ULTRASONIC	C512	64685	18023920-CARDI	CARDIOLOGY	R8.2190		02/10/05
806538	PANASONIC INDUST/MEDICAL GROUP	RECORDERS, TAPE, VIDEO	AG-MD830P	F5TH00229	18023920-CARDI	CARDIOLOGY	R8.2181	$3,840.00	11/10/95
807589	PANASONIC INDUST/MEDICAL GROUP	RECORDERS, TAPE, VIDEO	AG-MD830P	J8TC00250	18023920-CARDI	CARDIOLOGY	R8.2181	$3,840.00	04/11/01
807591	SONY ELECTRONICS INC MED SYST	VIDEO MONITORS	PVM-14M2U	2008021	18023920-CARDI	CARDIOLOGY	R8.2181	$0.00	04/11/01
807593	PANASONIC INDUST/MEDICAL GROUP	RECORDERS, TAPE, VIDEO	AG-MD830P	J8TC00242	18023920-CARDI	CARDIOLOGY	R2.1102	$3,840.00	04/11/01
808078	MEDICAL POSITIONING INC	ERGOMETERS, BICYCLE	50155A.B.	9909-16	18023920-CARDI	CARDIOLOGY	R8.2198F	$22,198.50	06/13/01
808745	CIVCO MEDICAL INSTRUMENT CO	WARMING UNITS, GEL	GW2E	4854	18023920-CARDI	CARDIOLOGY	R8.2198B	$85.00	12/11/97
810801	PHILIPS MED SYS CARDI & MON SYS	RECORDERS, TREND, TAPE, ECG	3100A	15263	18023920-CARDI	CARDIOLOGY	R8.2181	$1,500.00	11/20/01
810802	PHILIPS MED SYS CARDI & MON SYS	RECORDERS, TREND, TAPE, ECG	3100A	15268	18023920-CARDI	CARDIOLOGY	R8.2181	$1,500.00	11/20/01
810803	PHILIPS MED SYS CARDI & MON SYS	RECORDERS, TREND, TAPE, ECG	3100A	15278	18023920-CARDI	CARDIOLOGY	R8.2181	$1,500.00	11/20/01
810804	PHILIPS MED SYS CARDI & MON SYS	RECORDERS, TREND, TAPE, ECG	3100A	15280	18023920-CARDI	CARDIOLOGY	R8.2181	$1,500.00	11/20/01
810805	PHILIPS MED SYS CARDI & MON SYS	RECORDERS, TREND, TAPE, ECG	3100A	15376	18023920-CARDI	CARDIOLOGY	R8.2181	$1,500.00	11/20/01
810806	PHILIPS MED SYS CARDI & MON SYS	RECORDERS, TREND, TAPE, ECG	3100A	15385	18023920-CARDI	CARDIOLOGY	R8.2181	$1,500.00	11/20/01
810807	PHILIPS MED SYS CARDI & MON SYS	RECORDERS, TREND, TAPE, ECG	3100A	15450	18023920-CARDI	CARDIOLOGY	R8.2181	$1,500.00	11/20/01
810808	PHILIPS MED SYS CARDI & MON SYS	RECORDERS, TREND, TAPE, ECG	3100A	15210	18023920-CARDI	CARDIOLOGY	R8.2181	$1,500.00	11/20/01
810809	PHILIPS MED SYS CARDI & MON SYS	RECORDERS, TREND, TAPE, ECG	3100A	15466	18023920-CARDI	CARDIOLOGY	R8.2181	$1,500.00	11/20/01
810810	PHILIPS MED SYS CARDI & MON SYS	RECORDERS, TREND, TAPE, ECG	3100A	15470	18023920-CARDI	CARDIOLOGY	R8.2181	$1,500.00	11/20/01
810811	PHILIPS MED SYS CARDI & MON SYS	RECORDERS, TREND, TAPE, ECG	3100A	15473	18023920-CARDI	CARDIOLOGY	R8.2181	$1,500.00	11/20/01

16 ADDITIONS TO MEDICAL EQUIPMENT MANAGEMENT INVENTORY

Additions to the inventory are available as a query in TMS Enterprise System.

In the Asset Query screen select:
Status: ACTIVE
In the Purchase Info section, do an advanced query on ACCEPTED field (here you select a range of dates for additions to inventory)

UTMDACC Biomed Initial Inspection Form

Main **Asset #*:** **Asset Description:**

Purchase Info

Manufacturer:
Model:
Serial Number:

Location

Site Code:
Building Code:
Floor:
Location Desc:

Date Purchased:
Date Received:
Date Accepted:

Internal

Type*:
Category*:
Sub Category*:

Cost

Original Cost:
Replace Cost:

Account Code:
Account Desc*:
Skill: BMET
Status: Active

Eqpt Fct (E) | Clncl App (A) | PM Frq (P) | Risk # | Priority

Details

CAM No.
Special Test/Software Reference:

Service Manual? Location:
Operating Manual? Location:
Schematics/Parts List? Location:

Warranty

Start Date: End Date: Original PO:
Warranty Company:
Mailing Address:

Contact

Resource: Additional Info

PM

Scheduling: Calendar Frequency: Semi-Annual Next Due Date*:

Tasks

Priority : Task No.: Resource Assigned:

Main **Work Order #:** **WO TYPE*:** **Assigned:**

Time

Date	Resource	Hours Code	Hours	Stop Time	Billable	Comments

Materials

Warehouse	Item	Description	Avg. Cost	Qty Issue	Issue Date	Billable

Complete

Problem: Status*: Parts Cost:
Item: Sub Status*: PM Action: Labor Cost:
Action: Completion Date: Taks #: Total Cost:
Comments:
(Solution)

Function Test Passed? ESI Test Passed? Accessories included?

Tech Signature: **Accepted By:**

Authorized Signature: **Account Number:**

19 APPLICATION FOR EQUIPMENT ACCEPTANCE

Device: _____

Manufacturer: _____ Sales Representative: _____

Address: _____ Address: _____

City, State, Zip: _____ City, State, Zip: _____

Phone: _____ Phone: _____

Service: _____ Address: _____

City, State, Zip: _____ Phone: _____

1. Device is powered by?	
2. If 110V AC, does the device have a hospital grade plug or is it double insulated?	
3. Does the device meet AAMI electrical leakage conditions?	
4. Two (2) service manuals with schematics and a useable parts list will be included?	
5. Two (2) operator manuals will be included?	
6. Warranty period and any limitations are?	
7. Warranty period will begin following acceptance testing or?	
8. Is device rented, leased or under contract?	
9. If yes, service and preventive maintenance is provided by?	
10. Total number of years or months device has been on the market?	
11. Are any special connectors needed? (list)	
12. Are any special modifications needed to the premises? (list)	
13. Are any special services needed? (list)	
14. Are any special brackets or mounting hardware needed? (list)	
15. Are any batteries needed or used? (list)	
16. Please attach a list of all simulators, probes, cables, etc., needed for proper operation, along with name and address of manufacturer if different than previously identified.	
17. Recommended minimum calibration and preventive maintenance periods are?	
18. Fluid spill protection is (0-10, 0 is poor)?	
19. Device emits RF, x-rays, electromagnetic fields, etc.? Describe.	
20. Device is susceptible to RF, electromagnetic fields or power line interference? Describe.	
21. Device uses or may emit radioactive or toxic materials? Describe.	
22. Device is susceptible to mechanical jarring or vibration? Rate 0-10, with 0 being fragile.	
23. Number, type, and sizes of fuses? Easily accessible? Describe.	
24. Temperature operating range?	
25. Recommended method of cleaning and/or sterilization?	
26. Active components can be obtained locally? Exceptions?	
27. Total weight?	
28. Is factory service training available? Location and cost?	
29. On site in-service training? Cost?	
30. Number of year's manufacturer has been in business?	

Evaluated in-house? ❑ Yes ❑ No By whom? _____ Date: _____

THE UNIVERSITY OF TEXAS
MD ANDERSON
CANCER CENTER

Volume IV
Book F Environmental Health and Safety
Chapter 1 General Safety
Policy Number IV.F.1.10

Last Revised: 08/25/06

RENTAL MEDICAL EQUIPMENT MANAGEMENT POLICY

PURPOSE	The purpose of this policy is to ensure that medical equipment rented by the institution is safe for patient/operator use.
POLICY STATEMENT	It is the policy of The University of Texas M. D. Anderson Cancer Center to maintain a safe environment for all patients, employees, and visitors by inspecting rental medical equipment for safety and operational integrity before patient use.
SCOPE	The policy covers all employees involved in the inspection of rental medical equipment used by the institution.
DEFINITIONS	**Main Campus**—any patient care area that is part of the M. D. Anderson, Houston campus.
	Rental Agent—manufacturer, distributor, rental company, or other entity that rents medical equipment to the Texas Medical Center on a short- or long-term basis.

RENTAL MEDICAL EQUIPMENT MANAGEMENT PROCEDURE

EQUIPMENT RENTAL	1.	Rental Agents that provide rental equipment to the M. D. Anderson Main Campus will have their equipment checked (incoming electrical safety/functional inspection) by the Clinical Engineering department prior to use on a patient unless the Rental Agents can demonstrate compliance with required standards (see **Rental Medical Equipment Performance Requirements**).
RESPONSIBILITIES	2.	Clinical Engineering Manager:
		a. Rental Equipment Performance Requirements—the Clinical Engineering Manager will maintain/conduct performance requirement checks on rental agents, (see **Rental Medical Equipment Performance Requirements**) and maintain a record of results.
		b. Rental Agents—the Clinical Engineering Manager will maintain a current list of rental agents that comply with **Rental Medical Equipment Performance Requirements**.
		c. Documentation—Rental Agents will maintain electrical safety and operational integrity test documentation. These documents may be

		called for and reviewed at any time by the Clinical Engineering Manager.
		d. Documentation Review—The Clinical Engineering Manager will review rental agents documentation for completeness, compliance with performance requirements and/or trends that may indicate safety hazards.
		e. Annual Visit—The Clinical Engineering Manager will conduct annual visits to Rental Agent facilities using the following check list: 1. Random review of preventative maintenance documentation. 2. Observation of equipment flow: receiving, cleaning, decontamination, packaging, storage, and shipping. 3. Verify current calibration dates on test equipment. 4. Perform audit per **Rental Medical Equipment Performance Requirements**.
	3.	Clinical Engineering Technicians:
		a. Spot Checks—Clinical Engineering Technicians will randomly check rental equipment for electrical safety and operational integrity as they are performing scheduled Preventative Maintenance checks.
		b. The Clinical Engineering Manager will be notified of any equipment deficiencies found during these random checks.
		c. Deficiencies will be submitted to the Rental Agent for corrections.
PERFORMANCE REQUIREMENTS	4.	The Rental Agent will test, document, and label the equipment in accordance with the following:
		a. Manufacturer recommendations; and
		b. JCAHO standards
	5.	The Rental Agent will provide Clinical Engineering with their Policy & Procedure protocols as they relate to medical equipment preventative maintenance and test procedures.
	6.	The Rental Agent will provide Clinical Engineering with the preventative maintenance test procedures to be used and a schedule of testing frequency. Clinical Engineering will be notified of and will approve any changes in the testing procedure or frequency.
	7.	The Rental Agent will document inventory of all medical equipment rented to the main campus. Inventory will include: • Equipment Description • Equipment Manufacturer • Equipment Model • Equipment Identification Number • Department Renting Equipment • Delivery/Removal Dates • Preventative Maintenance Due Date
	8.	The Rental Agent will perform appropriate safety/operational tests on

		equipment prior to delivery to the Main Campus. The Rental Agent is to ensure all equipment is functional, accurate and poses no potential threat to the patient or medical staff.
	9.	The Rental Agent will include the following when labeling rental equipment: • Rental Agent Name • Next inspection due date • Inspector's name or initials
	10.	Upon request, Rental Agent will provide Clinical Engineering with documentation of the appropriate safety/operational tests performed prior to unit's delivery to Medical Center.
	11.	The Rental Agent will perform any periodic maintenance due on the equipment while it is within the main campus or replace it with properly inspected equipment that has a current inspection label.
	12.	All equipment provided by the Rental Agent is subject to inspection by Clinical Engineering.
	13.	Clinical Engineering will visit the Rental Agent facilities once a year to review the rental equipment maintenance program.
	14.	The Rental Agent will utilize test equipment that has current calibration.
	15.	The Rental Agent will utilize test equipment that has been calibrated by the manufacturer (or certified independent agent) and the calibration equipment utilized must be National Bureau of Standards traceable.
KEY WORD	1.	None.

REFERENCE:
JCAHO EC.6.10, EC.6.20

STRATEGIC VISION: From the following, please select the appropriate goal(s) applicable to this policy and identified in the 2005-2010 Strategic Vision:

Goal 1: **Enhance the excellence, value, safety and efficiency of our patient care.**

Goal 2: Enhance the quality of existing research programs and develop priority programs for the future.

Goal 3: Enhance the quality and outcomes of our undergraduate and graduate degree-granting programs, and our post-doctoral training programs.

Goal 4: Expand research addressing risk assessment, prevention and early detection of cancer and develop strategies to disseminate these findings.

Goal 5: Advance M. D. Anderson as an employer of choice.

Goal 6: Increase our mission-driven collaborations and outreach.

Goal 7: Safeguard and enhance our resources.

Approvals:

Committee Review

Committee:	Names:	Date:
Institutional Safety Committee		

Management Approval

(Policies/Procedures require the approval of two members of management - and at least one approver must be at the level of Associate Vice President or higher.)

Approved by (Name):	Title:	Date:
Linda D. Lee, DrPH, REM	EH&S Executive Director, Chairperson, Institutional Safety Committee	
David Callender, MD, MBA	EVP and Chief Operating Officer	
Leon Leach, MBA	Executive Vice President	
Margaret Kripke, PhD	EVP and Chief Academic Officer	

	Name:	Title:
Email Recipient:	1.	
	2.	
Policy Steward:	Tim Lecuyer	Policy Steward, Biomed/Clinical Engineering

History:

Issue Date:	03/98	Archival Record:	EH&S
Revision #1:	09/00	Archival Record:	EH&S
Revision #2:	10/00	Archival Record:	IP Database
Revision #3	01/04	Archival Record:	EH&S

Next Scheduled Revision: (mm/yy)

Notes: None.

Last Reviewed: 8/28/2007

ELECTRICAL SAFETY FOR PATIENT CARE POLICY

PURPOSE

The purpose of this policy is to provide guidance regarding the use of certain electrical devices in patient care areas at The University of Texas M. D. Anderson Cancer Center (M. D. Anderson).

POLICY STATEMENT

It is the policy of M. D. Anderson to strive to maintain safe electrical supply services within patient care buildings.

SCOPE

This policy covers all M. D. Anderson workforce members.

DEFINITIONS

Adapter (or adapter cord, or multiple outlet adapter) - Device used to connect an AC power cord plug to an AC power outlet having a different pin configuration and/or which permits more electrical devices to be connected to a power receptacle than the receptacle was designed to accommodate.

Asset ID Tag – Bar coded tags that are used to inventory patient medical equipment of any purchase value. (Examples: AHXXXXXX, 5XXXXX, BXXXXXX, 8XXXXX, & CLXXXXX)

Critical Care Area - Patient care areas where patients are subjected to invasive procedures and directly connected to line-operated medical devices. These areas may include surgery, intensive care, coronary care & catheterization.

Electrically Sensitive Patient - Any patient particularly sensitive to electrical hazards due to debilitating medical conditions, major loss of skin resistance due to use of wet dressings, presence of indwelling conductive catheters, probes with externally exposed intra-cardiac leads or similar conditions.

Extension Cord - Any electrical power supply cord not wired directly into a device and placed between the device and power outlets.

Inspection Sticker – A sticker used by the Clinical Engineering department to indicate that equipment has been inspected.

Non-Hospital Owned ("NHO") - Electrical devices not owned by M. D. Anderson, for instance, devices that are rented or leased.

Non Patient Care Areas - Business offices, corridors, lounges, day rooms, dining rooms, or similar areas typically not classified as patient care areas.

Patient Care Area - Critical areas defined above and general care areas where patients are expected to come in contact with ordinary electric appliances (lamps, beds, TVs, etc.) or be connected to medical devices. This includes patient rooms/treatment areas, DOES NOT INCLUDE NURSING STATIONS, as it is not intended as a general patient thoroughfare.

Patient Supplied Electric Medical Equipment – Any electrical medical device used by a patient, which was not provided to the patient by M. D. Anderson .

ELECTRICAL SAFETY FOR PATIENT CARE PROCEDURE

PROCEDURE

1. Only electrical devices meeting the electrical safety guidelines stated within this policy should be used at M. D. Anderson.

   Building Electrical Safety Inspection (ESI) is the responsibility of the Patient Care and Prevention Facilities Department Physical Plant (Facilities Management Division).

   Medical Equipment Preventive Maintenance (PM) is the responsibility of Clinical Engineering of the Patient Care Prevention Facilities Department (Facilities Management Division).

2. Electrical adapters which eliminate ground should not be used.

3. Extension cords should be inspected by Environmental Health & Safety prior to use. Where frequent or permanent use of extension cords is expected, a request for installation of a permanent power outlet(s) should be made for that location.

4. All hospital owned electrical medical devices used in patient care areas should receive an Incoming Inspection prior to installation and use.

5. All hospital owned electrical medical devices should comply with the Clinical Engineering Medical Equipment Management Program.

6. All patient care electrical medical equipment not displaying an M. D. Anderson Clinical Engineering inspection sticker should be removed from patient care areas.

7. Clinical Engineering should establish and maintain the medical equipment management program and maintain documentation on patient care electrical medical equipment.

8. All patient care electrical medical equipment that passes incoming inspection through Clinical Engineering, should be affixed with an M. D. Anderson Clinical Engineering inspection sticker indicating the due date of the next inspection:

9. All patient care electrical medical equipment that does not pass incoming inspection through Clinical Engineering should be removed from patient care areas unless or until the equipment has passed inspection.

10. With the approval of the Clinical Engineering, asset ID tags and an appropriate Clinical Engineering inspection sticker should be placed on certain long-term leased equipment for preventative maintenance and equipment history purposes. All other "NHO" equipment should not be tagged with an asset ID tag.

11. Clinical Engineering should follow the guidelines below for safety measurements:

    A. GROUND RESISTANCE; resistance of the ground from exposed metal surface to plug pin:
        1. ALL areas: 0.5 OHMS MAX

    B. LEAKAGE CURRENT; measurement is made with the ground broken and readings taken with device "ON" and with device "OFF". Highest reading is recorded.
        1. Patient Care Area/Equipment: 300 MICROAMPS MAX
        2. ALL Other areas: 500 MICROAMPS MAX

    C. REVERSE POLARITY: Clinical Engineering does not conduct reverse polarity testing, as it is not required by any regulatory agencies.

    D. LEAD LEAKAGE; (Patient Care) non-isolated between all leads and ground less than 100 microamps; between leads, less than 50 microamps.

E. ISOLATED; (Patient Care) between each lead and leads to ground less than 10 microamps with Ground Intact and 50 microamps with Ground Open.

F. LEAD ISOLATION; (Patient Care) flow of no more than 20 microamps when line voltage is applied between lead and ground, only performed during incoming inspection.

14. Clinical Engineering should complete scheduled inspections each month per the Medical Equipment Plan guidelines.

15. Inactive medical equipment that has been removed from service or salvaged should have a Clinical Engineering sticker attached to it indicating the date it was removed from service. Further, such devices should pass inspection by Clinical Engineering before being placed back into use.

16. Documentation, including service and/or safety documentation should be obtained from outside vendors every time equipment is serviced or transported.

DEPARTMENT DIRECTOR RESPONSIBILITIES

17. The Clinical Engineering department and Safety Committee will periodically audit and verify/validate compliance with this policy.

18. It will be the responsibility of those in applicable leadership roles, e.g. Department Directors, to ensure that this policy is administered within their department or area.

19. It will be the responsibility of those in applicable leadership roles, e.g. Department Directors, to ensure that all their staff involved with patient care receive education about electrical safety and electrically-sensitive patients on a yearly basis.

FACILITIES INFRASTRUCTURE INSPECTIONS (ESI)

20. **Infrastructure** is defined as installed building systems and includes permanently installed end-point electrical service devices used by building occupants.

21. **Infrastructure "Electrical Safety Inspections" (ESI)**: are regularly scheduled inspections of Patient Care spaces within M. D. Anderson and are designed to maintain optimum "environment of care." Devices covered under this program should be scheduled for inspection using the computerized Facilities Management preventive maintenance system. Electrical Safety Inspections include checks of the following permanently installed end-point electrical service devices used by building occupants:

- Receptacles,
- Switches, and
- Ground fault circuits interrupt (GFCI).

22. **Receptacles**:

Description: 110 or 220-volt plug-in receptacles that are either normal (white) or emergency (red) receptacles, which are located in the following locations:

- Critical Care areas: Operating Rooms, PACU, SICU, MICU;
- General Patient Care areas: Patient rooms, clinic or in-patient treatment rooms, Nurse Stations; or
- Wet locations: Mechanical rooms, electrical closets, janitor closets soiled linen closets.

A. **Inspection Procedure**: A qualified Technician should perform the following checks:
   - Physical integrity condition; visual check,
   - Continuity of grounding circuit,
   - Correct polarity of hot and neutral wires, and
   - Retention force of grounding blade ≥ 4 oz.

B. **Inspection Frequency**:
   - Critical Care areas: Every 6 months;
   - General Patient Care areas: Annually; and
   - Wet locations: Quarterly

23. **Switches**:

Description: Installed equipment activation devices (usually light switch or fan switch) located in the following locations:

- Critical Care areas: Operating Rooms, PACU, SICU, and MICU;
- General Patient Care areas: Patient rooms, clinic or in-patient treatment rooms, Nurse Stations; or
- Wet locations: Mechanical rooms, electrical closets, janitor closets, soiled linen closets.

A. **Inspection Procedure**: A qualified Technician should perform a visual check of the physical integrity condition of the device.

B. **Inspection Frequency**:

- Critical Care areas: Every 6 months;
- General Patient Care areas: Annually; and
- Wet locations: Quarterly

24. **Ground Fault Circuit Interrupt (GFCI)**:

Description: GFCI 110 or 220 volt receptacles located within M. D. Anderson. These are typically patient bathroom receptacles within 6 feet of a plumbing fixture.

A. **Inspection Procedure:** With the internal circuit breaker in the closed position, depress the "TEST" button on the device to induce a 6 milliamp flow to ground. If the circuit is interrupted, the device passes the test. Reset the internal circuit breaker to continue usage.

B. **Inspection Frequency**:

- Critical Care areas: Every 6 months;
- General Patient Care areas: Annually; and
- Wet locations: Quarterly.

OUTSIDE MAINTENANCE/ SERVICE CONTRACTS

25. It will be the responsibility of those in applicable leadership roles, e.g. Department Managers, to ensure that all outside maintenance and/or service contract agreements are appropriately adhered to. All scheduled preventive maintenance checks as indicated in such contracts are the responsibility of the Department Managers which the equipment is in.

PATIENT SUPPLIED ELECTRIC MEDICAL EQUIPMENT

26. The use of patient supplied electric medical equipment in inpatient areas is generally discouraged. Because of numerous factors, patient supplied electric medical equipment may not be safe for use at M. D. Anderson.

27. If an M. D. Anderson physician determines that it is in the best interest of the patient to use patient supplied electric medical equipment while inpatient at M. D. Anderson, then a Patient Supplied Electric Medical Equipment Form (see attached form 1.1) should be completed and filed in the patient's medical record.

28. Nursing staff should confirm the physical condition of applicable electric medical devices by verifying that:
    A. There is no broken case(s) and the electrical cord is fastened at both ends.
    B. The power cord jacket is completely intact, not frayed, cut or split.

29. Patient owned heating pads, electric blankets, & portable heaters should not be used at M. D. Anderson.

30. The Clinical Engineering Department shall not be responsible for electrical safety, performance verification, or repairs on any patient supplied electric medical equipment.

    On a case-by-case basis, Clinical Engineering may provide consultation regarding patient supplied electric medical equipment, but this consultation is not meant to verify electrical safety, performance or fitness for use.

ATTACHMENTS:

Form 1.1: The University of Texas M. D. Anderson Cancer Center Patient Supplied Electric Medical Equipment Form

REFERENCES:

Healthcare Facilities Handbook, 2005 edition
National Fire Protection Agency (NFPA 99), 2005 edition

STRATEGIC VISION:

Goal 1: Enhance the excellence, value, safety and efficiency of our patient care.

THE UNIVERSITY OF TEXAS
MD ANDERSON
CANCER CENTER

Volume IV
Book F Environmental Health and Safety
Chapter XX
Policy Number XX

Last Revised: 08/25/06

CLINICAL ALARMS POLICY

PURPOSE	To define a policy regarding the use of alarms on medical equipment and monitoring systems providing patient care.
POLICY STATEMENT	It is the policy of the University of Texas M. D. Anderson Cancer Center that all alarm systems incorporated into medical equipment and into patient monitoring systems must be activated whenever the piece of equipment or monitoring system is in use.
	Alarm limits must be set within an acceptable range (see attached inventory for settings and ranges) based upon the individual patient's clinical condition so that a significant change in the patient's condition or an abnormality in the operating condition of the piece of medical equipment applied to the patient will trigger an alarm.
	The volume level of all such alarms must be sufficiently audible with respect to distances and competing noise to be heard by the clinical staff in the immediate patient care area.
	At no time will alarms be disabled or inactivated, nor will alarm limits be set to such extremes so that they fail to detect significant changes in the patient's condition or operational condition of the equipment.
	This policy is in accordance with the Joint Commission for the Accreditation of Health Care Organizations (JCAHO) compliance requirements.
SCOPE	This policy covers all alarm systems incorporated into medical equipment and patient monitoring systems, triggered by physiologic changes in a patient or by variations in measured parameters of the medical equipment directly applied to the patient. This shall apply to all University of Texas M.D. Anderson Cancer Center owned and operated facilities.
DEFINITIONS	**Clinical Alarms**—Alarm systems (audible and/or visible) that are either built in or attached to medical equipment and monitoring systems and that are triggered by physiologic changes in the patient or by variations in measured parameters of medical equipment directly applied to the patient.

CLINICAL ALARM PROCEDURE

PROCEDURE	1.	Before a piece of medical equipment or monitoring system is used, the clinician using the equipment must be familiar with its operation, including knowledge of incorporated alarms and any equipment self-check procedures.
	2.	All alarm systems incorporated into or attached to the medical equipment or patient-monitoring systems must be activated whenever the piece of equipment or monitoring system is in use.
	3.	Alarm limits must be set within an acceptable range (see attached inventory for settings and ranges) based upon the individual patient's clinical condition so that a significant change in the patient's condition or an abnormality in the operating condition of the piece of medical equipment applied to the patient will trigger an alarm. In setting alarm limits, clinical staff should also take into consideration the need to minimize false alarms.
	4.	The volume level of all such alarms must be sufficiently audible with respect to distances and competing noise to be heard by the clinical staff in the immediate patient care area. This may require that alarm volumes be adjusted upward at certain times of the day based upon the noise level and activity in the patient care area. The volume of an alarm system may need to be supplemented to be audible in the immediate care area through modification of the alarm system by Clinical Engineering personnel, or by adding a supplemental system to the equipment alarm. This may be accomplished by connecting the alarm system to the nurse call system.
	5.	Alarms should not be deactivated from a remote site such as from the central console without first investigating the cause of the alarm. The clinical staff member should directly visualize the patient and evaluate the reason for the alarm before re-setting it. The alarm may be muted or suspended for a brief period of time only when a staff member is present and is monitoring, evaluating, and/or treating the patient. Before turning attention away from the patient, the alarm must be reactivated.
	6.	A Clinical Alarms Inventory (see attachment) must be maintained by Clinical Engineering and reviewed annually, whenever new/ replacement equipment is placed into service, and whenever there is a change in the physical environment of the patient care area in which the equipment is used.
	7.	Appropriate protocols must ensure Clinical Engineering technical review of equipment requiring alarms within the framework of the procurement process, to prevent procurement of equipment without alarm interfacing provisions.
EXCEPTIONS		None.
RESPONSIBILITY	1.	Individual patient care areas must be responsible for development, maintenance and updates of protocols per institutional policy (see attached inventory for settings and ranges) for verifying alarm operation before and during use (including a focus on the background noises that

		may prevent clinical staff from hearing alarms) and training in the operation of clinical alarm systems. Staff competency includes knowledge of alarm activation and appropriate alarm limits based upon type and condition of the patient and environmental setting. Additionally, patient care areas must develop protocols for any specialized equipment, unique to their areas, in consultation with Clinical Engineering.
	2.	All clinical staff must adhere to the correct protocol for the respective patient care areas when responding to clinical alarm systems and are responsible for notifying Clinical Engineering of any malfunctions of clinical alarm systems.
	3.	Clinical Engineering shall perform Preventive Maintenance (PM) on equipment and monitoring systems, maintain documentation of PM performance and report monthly to the Institutional Safety Committee. All clinical alarms that are integrated into medical equipment and monitoring systems must be inspected and tested along with the other components of the equipment as defined by the manufacturer's recommendations and the PM inspection protocol. All monitors and alarms used must be calibrated and maintained regularly according to the manufacturer's instruction and the recommended service schedule. Equipment found to have non-functioning alarm systems must be immediately removed from service until repaired. In addition, Clinical Engineering personnel will review self-check log sheets during Zonal Inspection Plan (ZIP) Rounds conducted semi-annually in patient care areas.

REFERENCE:
JCAHO Standards Manual 2004

STRATEGIC VISION: From the following, please select the appropriate goal(s) applicable to this policy and identified in the 2005-2010 Strategic Vision:

Goal 1: **Enhance the excellence, value, safety and efficiency of our patient care.**

Goal 2: Enhance the quality of existing research programs and develop priority programs for the future.

Goal 3: Enhance the quality and outcomes of our undergraduate and graduate degree-granting programs, and our post-doctoral training programs.

Goal 4: Expand research addressing risk assessment, prevention and early detection of cancer and develop strategies to disseminate these findings.

Goal 5: Advance M. D. Anderson as an employer of choice.

Goal 6: Increase our mission-driven collaborations and outreach.

Goal 7: Safeguard and enhance our resources.

Approvals:

Committee Review

Committee:	Names:	Date:
Institutional Safety Committee		

Management Approval

(Policies/Procedures require the approval of two members of management - and at least one approver must be at the level of Associate Vice President or higher.)

Approved by (Name):	Title:	Date:
Linda D. Lee, DrPH, REM	EH&S Executive Director, Chairperson, Institutional Safety Committee	
Thomas Burke, MD	EVP and Physician-in-Chief	
Leon Leach, MBA	Executive Vice President	
Margaret Kripke, PhD	EVP and Chief Academic Officer	

	Name:	Title:
Email Recipient:	1.	
	2.	
Policy Steward:	Sharath Rao	Policy Steward, EH&S

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Next Scheduled Revision: (mm/yy)

Notes: None.

28 USE OF CLINICAL ALARMS ON MEDICAL EQUIPMENT

POLICY:

It is the policy of UTMDACC to assure that all clinical alarms and medical equipment alarm systems utilized for patient care are properly operational and alarms are activated when the appropriate settings are in use.

PROCEDURE:

- Routine preventive (or established maintenance strategy) maintenance and testing of clinical alarms and alarm systems associated with medical equipment will be performed by the Clinical Engineering/Biomedical Department:
    - The Clinical Engineering/Biomedical staff will inventory all equipment/devices that are equipped with an alarm that is designed to elicit a response.
        - This includes all medical (patient care) equipment such as ventilators, infusion pumps, anesthesia gas monitors, physiological monitors, etc., as well as safety and security alarms such as infant abduction alarms, patient “bed exit/fall alarms”, etc.
        - Each piece of medical equipment/device to be utilized for patient care will be inventoried for risk.
        - Each safety/security alarm throughout the institution will be inventoried for risk.
    - Assess each device and assign a risk score based on inherent risk of the device (or safety/security system) failing to alarm or failing to draw the attention of staff (staff do not respond to alarm).
        - Risk scoring risk will be assigned on a 0 - 5 scale, with **0** (zero) being **no risk** to patient **5** (five) being **serious risk** including possible death to the patient.
    - Testing of all equipment/devices and safety/security systems will be performed, starting with devices with the highest risk potential. Testing is designed to ensure the alarming mechanism (audible, visual, both) is functioning according to the manufacturer's specifications.

- Upon conclusion of the operational testing, periodic functional (human factor) testing will be conducted.
    - Functional testing will be performed by periodic activation of the alarm on the device/equipment in a patient care area for equipment on the inventory list.
    - The functional test will be conducted on a piece of equipment/device that is not in use on a patient.
    - The device/equipment will be brought to the patient care unit for evaluation of the staff's response to the alarm.
        - A corrective action plan will be developed by an interdisciplinary team (staff from the specific patient care unit, Clinical Engineering/Biomedical staff, Patient Safety Committee representative) upon identification of any environmental noise, staffing or other issues that prevent staff from hearing and responding to the alarm.
    - A corrective action plan will be developed collaboratively by Clinical Engineering/Biomedical Department and the Patient Safety Committee (or representative thereof) and a representative (as appropriate) from the patient care unit for any identified malfunction of safety/security alarm systems.
- Patient care staff will perform routine testing of clinical alarms prior to use of medical equipment/devices on the patient population:
    - Patient care staff will manually set off alarms during operational assessment of all medical devices/equipment to assure proper functioning of the equipment and associated alarms prior to use on the patient.
        - An environmental assessment of the alarm will be performed to assure the alarm can be heard within an appropriate distance and with competing noise within the unit where the medical device/equipment is being used. The environmental assessment will include assurance that any visual aspects of the alarm system are working properly when activated.
- Patient care staff will verify and reset if necessary the alarm parameters at the beginning of each shift, when the nurse returns from breaks and when the patient is turned or moved.

- Alarm parameters are patient specific. Parameters should be set at 5 - 10% above and below expected rate.

- Patient care staff will assure that direct observation of the patient is routinely conducted to avoid singular dependence on alarm systems.

- Staffing on all patient care units will consider the amount and complexity of medical equipment/devices utilized for patient care to assure sufficient staff available to assess, operate, hear and respond appropriately to clinical alarms at all times. The staffing ratio will be appropriate to the complexity of the medical equipment/devices in use and the acuity of the patient.

- All staff who utilize or maintain medical equipment/devices with clinical alarm systems will be properly oriented to the equipment/device and the alarm and trained on its use.

  - Patient care staff must demonstrate both physical knowledge of the operational aspects of the equipment/device and alarm, and the physiological aspects as to why alarms become activated related to the specific equipment/device in use for the patient.

  - Clinical Engineering/Biomedical staff must demonstrate physical knowledge of the mechanical aspects of the equipment/device alarm system.

  - All staff using and/or maintaining medical equipment/devices with related alarm systems must be assessed and proven competent to operate the equipment/device and manage its associated alarm mechanism prior to use of that equipment/device.

    - For all equipment/devices with clinical alarms, staff competency assessment will be conducted prior to initial use of the equipment/device and annually thereafter.

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Last Revised: 06/21/2004

ELECTRICAL EXTENSION CORD POLICY

PURPOSE

The purpose of this policy is to ensure safe usage of electrical extension cords in all patient care areas, sleeping areas, laboratory areas, and office areas.

POLICY STATEMENT

It is the policy of M. D. Anderson to use electrical extension cords that meet requirements to protect building occupants from the dangers or the effects of fire in accordance with Joint Commission on Accreditation of Health Care Organizations (JCAHO), the City of Houston Fire Code, and the Life Safety Code.

Environmental Health and Safety reserves the right to review, inspect, or decline requests or usage of electric extension cords that may be deemed illegal or unsafe.

SCOPE

The policy covers all employees, to include faculty.

DEFINITIONS

Life Safety Codes – standards set forth by the National Fire Protection Association that provides minimum building design, construction, operation and maintenance requirements needed to protect building occupants from the dangers of the effects of fire.

RESPONSIBILITY

It is the responsibility of all M. D. Anderson personnel to ensure compliance with this policy. The Environmental Health and Safety Department will also periodically inspect each area. Violators will be issued a “Safety Violation.”

EXCEPTIONS

Any exceptions to established policy will be at the discretion of the Institutional Safety Committee. This committee on an annual basis must review all exceptions.

REFERENCES:

National Fire Protection Association’s Life Safety Codes
City of Houston Fire Code

Committee Reviews:	Institutional Safety Committee			Date:	
Approved by:	Leon Leach, MBA	Title:	Executive Vice President	Date:	
Approved by:	Thomas Burke, MD, BS	Title:	Senior Vice President & Chief Operating Officer, ad interim	Date:	
Approved by:	Margaret Kripke, Ph.D.	Title:	Executive Vice President and Chief Academic Officer	Date:	
Approved by:	Linda D. Lee, MS, REM	Title:	EH&S Executive Director, Chairperson, Institutional Safety Committee	Date:	
Approved by:	Otto Akers	Title	Policy Steward, EH&S	Date:	

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36 USE OF ELECTRICAL EQUIPMENT IN OXYGEN ENRICHED ENVIRONMENTS

PURPOSE:

To establish use of electrical equipment in an oxygen enriched environment.

DEFINITION:

Oxygen enriched atmosphere: An atmosphere in which the oxygen concentration exceeds 21 percent by volume or 160 millimeters of mercury partial pressure.

GENERAL INFORMATION:

Electrical equipment such as electrocardiographs, defibrillators, pacemakers, radiographic equipment, electronic stethoscopes, electrical beds, radios and television sets (including remote controls), call button switches, communication equipment (including hearing aids, pillow speakers, telephone handsets), hair dryers, electrically powered nebulizers, vapor generators and battery-powered equipment such as flashlights, laryngoscopes and endoscopic instruments, (often employed on patients who are receiving respiratory therapy treatments). This equipment is a source of ignition if electrical defects are present because of arcing and excessive temperatures generated by the flow current.

ELECTRICAL EQUIPMENT:

- Electrical equipment used within an oxygen enriched atmosphere shall be listed for such use.

- Electrical equipment not marked or listed for use in oxygen enriched atmosphere may be used in the vicinity, if affixed to the bed or wall in such a location that it will not be subject to an oxygen enriched atmosphere.

- Electrical apparatus not listed for use within an oxygen enriched atmosphere, which might be introduced inadvertently into such an atmosphere, shall be excluded from the site of administration.

- A defective electrical apparatus shall be tagged and repaired or discarded.

- Prudent practice may dictate that the administration of oxygen be terminated temporarily during cardiac defibrillation.

- Toys are of special emphasis in the pediatric area. No battery-operated toys or friction toys which create sparks will be allowed in oxygen enriched environments.

- Monitor use of personal electrical items such as electronic games, tape recorders, radios, hair dryers, curlers, electric shavers, coffee pots or any other personal device.

39 EQUIPMENT CONDITION

POLICY:

All appropriate personnel will be responsible for assessing the condition of equipment in their use.

PROCEDURE:

- All Equipment:
  - The overall appearance of the item must be up to departmental standards.
  - The interior and exterior of the equipment must be free of rust, corrosion solutions, lint, dents and deposits.
  - Control knobs, mechanical locks and levers must be securely attached to the driven element and properly indexed.
  - Doors, drawers, panels, shelves, catches, latches, hinges, stops, door pulls, handles, knobs and casters must be properly tightened or adjusted to operate smoothly.
  - Nuts, bolts, screws and other hardware must be tight and in good condition.
  - Component holders, clips and receptacles must be intact and properly adjusted.
  - The Operator's Manual will be on hand in the department utilizing the equipment.
- Items Which Involve Positive or Negative Pressure (i.e., Gases):
  - Conductivity will be verified in accordance with the National Fire Protection Association (NFPA) Handbook.
  - Rubber parts, components and fittings must exhibit original elasticity and shape. They must be free of cracks, splices, punctures and faulty fittings.
  - High pressure tubing must be free of leaks and frayed covering. All fittings and connections must be in good condition and securely attached to hose ends.
  - All temperature indicators must be checked to ensure accuracy.
  - All controls, regulators, flow meters and flush valves must be properly adjusted to accurately regulate the flow of gas.
  - Safety and "pop-off" valves must be in proper operating condition.
  - Glass and plastic covers on meters, inspection ports and containers must be free of cracks and chips; they must be clean and properly positioned for leak-free operation.

- Air evacuation systems must be capable of maintaining the desired vacuum within the design limitations.

- Grounding systems must be of the approved type and properly installed.

- Mechanical Equipment:

  - All chains, gears, bearings and bearing surfaces must be free of excessive wear and must be properly adjusted.

  - All gears must be free of excessive back lash.

  - Hydraulic systems, with their trips, locks, stops and release mechanisms, must be free of excessive wear and must be properly adjusted. Fluids must be at their proper levels and all systems must be free of leaks.

  - Casters must be checked and lubricated with general purpose lubricant.

40 EQUIPMENT SAFETY OPERATOR'S RESPONSIBILITY

POLICY:

- The following precautions will be used while operating equipment:
    - Operator will be alert to situations which may damage equipment or injure personnel.
    - Sufficient space is required around and above all mechanical equipment and electrical services to permit safe operation and to encourage good maintenance.
    - Operator shall be familiar with the normal equipment sounds to be able to detect the abnormal.
    - Operator shall investigate and report to Clinical Engineering Department abnormalities indicated by erratic meter responses, electrical flashing or arcing, burning smell, unusual grinding sounds of gears or other evidence of improper operation.
    - The following list of general safety factors will be continuously monitored:
        - Proper grounding of equipment.
        - Current Biomedical Engineering Green Tag
        - Accuracy of critical timing devices.
        - Adequate physical mounting for support of installed items.
        - Proper operation of safety valves.
        - Serviceable good condition of electrical cords.
        - Calibration of systems whose accuracy is absolutely essential in treatment or diagnosis.